

# FDA Requirements for Medical Technology

The U.S. Food and Drug Administration (FDA) employs a risk-based approach to regulating medical technology where the level of requirements to determine a device or diagnostic's safety and effectiveness is commensurate to its risk.

## Premarket Requirements

### Class I Low Risk



Bandages



Examination  
Gloves



Manual  
Wheelchairs

Most exempt from premarket  
submission requirements

### Class II Moderate Risk



Contact  
Lenses



Ultrasound Scanners



X-Ray  
Machines

#### Premarket Clearance 510(k)

Must demonstrate "substantial  
equivalence" to one or more devices  
legally marketed in the U.S.

Information in a 510(k)  
submission includes:

- Bench Testing
- Animal Studies  
(if deemed necessary by FDA)
- Batteries of non-clinical tests  
(biocompatibility, shelf-life, shock  
and vibration, temperature cycling,  
etc.)
- Tests demonstrating conformance  
with relevant national and  
international standards
- Any additional requirements  
specified by FDA, including clinical  
studies

### Class III High Risk



Artificial  
Heart Valves



Defibrillators



Spinal  
Implants

#### Premarket Approval Applications (PMA)

Must establish a "reasonable  
assurance of safety and  
effectiveness" as demonstrated  
by valid scientific evidence.

A complete PMA  
application will include:

- Results of any clinical studies
- Description of manufacturing  
& processing
- Description of the device  
including components,  
ingredients, properties, and  
principles of operation
- Full reports of all known  
information on the device's safety  
and effectiveness
- Results of non-clinical trials  
(bench/animal testing)
- Proposed professional and  
patient labeling
- A summary of safety and  
effectiveness data

